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Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 00-00-00
Baltimore, Maryland 21244-1850

Prescription Drug Data Collection (RxDC) Reporting Instructions

Section 204 Data Submission Instructions
for the 2020 Reference Year

Paperwork Reduction Act Statement
According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. The valid OMB control number for this information collection is 0938-XXXX. The time required to complete this information collection is estimated to average 4,731 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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1 Overview

1.1 What is the RxDC Report?

In these instructions, the term RxDC Report refers to the data submission required under Section 204 of Division BB, Title II (Section 204) of the Consolidated Appropriations Act, 2021 (CAA).[1] The Rx stands for Prescription Drug and the DC stands for Data Collection.

Section 204 requires group health plans (plans) and health insurance issuers (issuers) offering group or individual health insurance coverage to submit information about prescription drugs and health care spending to the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (the Departments). In addition, the Director of the Office of Personnel Management (OPM) requires Federal Employees Health Benefits Plan (FEHB) carriers to submit section 204 data to HHS. The Centers for Medicare & Medicaid Services (CMS) is collecting section 204 data submissions on behalf of the Departments and OPM.

The implementing regulations for the Section 204 data collection are at 5 CFR part 890, 26 CFR part 54, 29 CFR part 2590.725-1 to 2590.725-3, and 45 CFR part 149.

1.2 Who is required to submit the RxDC report?

Required to Submit	Not Required to Submit

• Health insurance issuers offering group coverage
• Health insurance issuers offering individual market coverage, including:
  o Student health plans
  o Plans sold exclusively outside of the Exchanges
  o Individual coverage issued through an association
• Fully-insured and self-funded group health plans, including:
  o Non-federal governmental plans, such as plans sponsored by state and local government
  o Church plans that are subject to the Internal Revenue Code
  o FEHB plans
	• Account-based plans, such as health reimbursement arrangements
	• Excepted benefits[2] including but not limited to:
	  o Short-term limited-duration insurance
	  o Hospital or other fixed indemnity insurance
	  o Disease-specific insurance
	• Medicare advantage plans
	• Medicare plans
	• Medicaid plans
	• State children's health insurance program plans
	• Basic Health Program plans

These requirements apply regardless of whether a plan is considered a grandfathered or grandmothered health plan.[3]

[1] The CAA is available at https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf

[2] PHS Act 2722(b) and (c), ERISA Section 732, and Code Section 9831.

[3] Grandmothered plans, sometimes referred to as transitional plans, are non-grandfathered plans in the individual and small group market that were issued prior to January 1, 2014, and for which CMS announced it will not take enforcement action with respect to certain market requirements. See Bulletin: Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies, available at https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2022.pdf.

1.3 Can a vendor submit data on my behalf?

Plans, issuers, and FEHB carriers (carriers) can contract with issuers, Third-Party Administrators (TPAs), Pharmacy Benefit Managers (PBMs), or other third party vendors to submit data on their behalf. An entity that submits some or all of the required information is called a **reporting entity**. In these instructions, "you" generally refers to the reporting entity.

> **What is a reporting entity?**
> An entity that submits some or all of the required information is called a **reporting entity**. In these instructions, "you" generally refers to the reporting entity.

1.4 When is the deadline?

The deadline for the 2020 reference year is December 27, 2021. The deadline for subsequent reference years is June 1st of the calendar year immediately following the reference year. A **reference year** is the year of the data that is in your RxDC report. For example, the RxDC report for the 2020 reference year means the information in the report is based on what happened in 2020.

For the 2020 and 2021 reference years: The Departments are deferring enforcement of the requirement to submit Section 204 data for the 2020 and 2021 reference years. The deadline for data submission for reference years 2020 and 2021 is December 27, 2022.[4] You may submit data prior to that date.

> **What is a Reference Year?**
> The reference year is the year of the data that is in your RxDC report. For example, the RxDC report for the 2020 reference year means the information in the report is based on what happened in 2020.

1.5 What files are required?

Plan Lists

The plan list files are (P stands for Plan):

P1. Individual and student market plan list
P2. Group health plan list
P3. FEHB plan list

The data dictionary and file layouts are available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection.

Data Files

Create aggregate data files by combining the information of multiple plans. For example, if you are reporting on behalf of 10 group health plans, list them separately in the plan list but combine their data in the data files.

The data files are (D stands for Data):

D1. Premium and Life-Years
D2. Spending by Category
D3. Top 50 Most Frequent Brand Drugs
D4. Top 50 Most Costly Drugs

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[4] See FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Part 49, Q12, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf and https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

D5. Top 50 Drugs by Spending Increase
D6. Rx Totals
D7. Rx Rebates by Therapeutic Class
D8. Rx Rebates for the Top 25 Drugs

The data dictionary and file layouts are available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection.

Narrative Response

See Section 8 below for information on the narrative response.

2 Data Submission

2.1 Where do I submit my data?

Submit data through the RxDC module in the Health Insurance Oversight System (HIOS). HIOS is an application within the CMS Enterprise Portal at https://portal.cms.gov/portal/.

Do I need to create a HIOS Account?
You do **NOT** need to create a CMS Enterprise Portal or HIOS account if:

- You already have a HIOS account, or
- You are not uploading any files (because an issuer, TPA, PBM, or other reporting entity is uploading files on your behalf).

The full instructions for creating your CMS Enterprise Portal and HIOS account are in the **HIOS Portal User Manual** located at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources#Content_Requirements_for_Plan_Finder. The **RxDC Module User Manual** is available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection

Overview of the submission process:

1. **Create an account** in the CMS Enterprise Portal, if you do not already have one.
   - Account creation includes identity verification and may take several days to process.
   - CMS recommends creating your account three weeks in advance of the RxDC submission deadline.
2. **Request access to HIOS** within the CMS Enterprise Portal.
   - Allow one business day for the access request to be approved.
3. **Register your organization** in HIOS (or associate yourself with an existing organization in HIOS).
   - If you are reporting on behalf of another entity (plan, issuer, or carrier), do NOT associate yourself with those entities during this step. (Identify those entities when you start your submission in the RxDC module.)
4. **Request a role** for the RxDC module within HIOS.
   - It may take 1-2 business days for CMS to approve your request.
5. **Submit your RxDC files** in the RxDC HIOS module.
   - Upload your files.
   - Review and submit your data.

Help Desk
If you have questions about submitting your data, contact the HIOS Help Desk at 1-855-267-1515 or

CMS_FEPS@cms.hhs.gov. Even if your question isn't about using HIOS, the HIOS help desk will route your question to the right person to help you.

You can typically expect a response within the same day and a full resolution within 1-2 weeks. Please build this into your data preparation time.

2.2 Can I have multiple reporting entities submit my data

Yes. A plan, issuer, or carrier can allow multiple reporting entities to submit on its behalf. For example, a self-funded group health plan may contract with a TPA to submit the Spending by Category data file (D2) and separately contract with a PBM to submit the Top 50 Most Costly Drugs file (D4). The submission for a plan, issuer, or carrier is considered complete if CMS receives all required files, regardless of who submits the files.

Multiple reporting entities should not submit the *same* data file for a plan, issuer, or carrier. For example, a TPA and PBM should not both submit D2 for the same group health plan. The HIOS system does not automatically prevent duplicate submissions of the same file. CMS will check whether there are duplicate files after the submission deadline.

To preserve confidentiality, a reporting entity can view only the files that it uploads. It cannot view files uploaded by a different reporting entity even if the information is related to the same plan, issuer, or carrier. For example, if a TPA uploads D2 and a PBM uploads D4 for the same group health plan, the TPA can only see D2 and the PBM can only see D4. The group health plan cannot see either D2 or D4. The plan should contact its reporting entities directly if the plan wants to see the data uploaded on its behalf.

2.3 How do I know if a reporting entity actually submitted my data?

Currently, no mechanism exists for CMS to notify plans, issuers, or carriers that data has been submitted on their behalf. To confirm submission, plans, issuers, and carriers should contact their reporting entities directly.

The plan, issuer, or carrier has the ultimate responsibility to make sure its data is submitted and that the data is accurate. This is true even if it contracts with one or more reporting entities to submit the data. The one exception is if a fully-insured group health plan contracts with an issuer to report its data, in which case the ultimate responsibility to report is on the issuer rather than the plan.

3 Data Aggregation

3.1 Market Segment Aggregation

Reporting entities will aggregate data according to market segment. The following table has the names and abbreviations for the market segments. Use the market segment abbreviations in your data files.

Market Segment	Abbreviation
Individual market, excluding the student market	Individual market
Student market	Student market
Fully-insured small group market	Small group market
Fully-insured large group market, excluding the FEHB line of business	Large group market
Self-funded group health plans offered by small employers	SF small employer plans
Self-funded group health plans offered by large employers	SF large employer plans
FEHB line of business	FEHB plans

The market segments are mutually exclusive. Do not report the same data in more than one market segment.

- For **mixed-funded plans**, which generally self-fund some benefits and fully insure other benefits, report the self-funded business in the self-funded market segment and the fully-insured business in the fully-insured market segment. For example, suppose a large employer self-funds the pharmacy benefit of a plan and purchases insurance for the medical benefits. In this case, the pharmacy benefits would be attributed to the market segment for self-funded large employer plans and the medical component of the same plan would be attributed to the fully-insured large group market.
- For "**minimum premium" plans** and similar hybrid arrangements that mimic key aspects of fully-insured arrangements, or that comply with state insurance laws regarding mandated benefits, report the business as fully-insured.[5]
- For **level-funded plans**, report the business as self-funded.

Determining Employer Size

For fully-insured plans, report data in the market segment used in the issuer's Medical Loss Ratio (MLR) report. For self-funded plans and FEHB plans that are not fully-insured, follow the MLR reporting instructions to determine employer size.[6] If the reporting entity for a self-funded plan doesn't have the necessary information to follow the MLR reporting instructions, the entity is permitted to use a reasonable estimate of employer size.

A reasonable method to estimate employer size for a self-funded plan is to divide the number of employees in the plan by 0.73.[7] For example, if 40 employees are covered by a plan, then the estimated employer size is 55 (40 ÷ 0.73 = 55). If you use an estimate for employer size for a self-funded plan, describe the method you used in your narrative response. If you use an estimation method other than the one described here, explain why you believe it is a reasonable method.

3.2 State Aggregation

The state aggregation rules for RxDC are similar to the requirements in the MLR reporting form instructions. In general, a reporting entity should report fully-insured business in the state where the policy was issued. For self-funded plans, the reporting entity should generally report the data in the

[5] "Minimum premium" generally have regular fixed premium or funding payments, often based on past experience, and limit the plan sponsor's liability for claims.
[6] The MLR reporting form instructions are available at https://www.cms.gov/cciio/resources/forms-reports-and-other-resources#Medical_Loss_Ratio. The most recently published instructions are at the bottom of the section.
[7] The divisor is based on estimated take-up rates from the National Compensation Survey, published by the Bureau of Labor Statistics. A take-up rate is the percentage of workers with access to a plan who participate in the plan. We used the healthcare take-up rate for employers with fewer than 100 employees. See Table 10 at https://www.bls.gov/ncs/ebs/benefits/2021/employee-benefits-in-the-united-states-march-2021.pdf.

state where the plan sponsor has its principal place of business. When a plan covers employees in multiple states, or when coverage is sponsored by a group trust, association, or multiple employer welfare arrangement (MEWA), the reporting entity should follow the instructions below.

Coverage in Multiple States
For self-funded coverage that is not provided through a group trust, association, or MEWA, report the data in the state where the plan sponsor has its principal place of business. For fully-insured plans, report the data in the state where the policy was issued. For individual market business sold through an association, report the data in the state where the certificate of coverage was issued. For FEHB carriers that are not associated with an issuer, TPA, or other third party vendor and that offer coverage in multiple states, report the data in the state where the policy was issued or where the carrier has its principal place of business.

Employer Business through Group Trust, Association, or MEWA
For health coverage provided to plans through a group trust or MEWA, report the data in the state where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an "employer" under Employee Retirement Income Security Act of 1974 (ERISA) section 3(5) for purposes of sponsoring the plan) has its principal place of business or the state where the association is incorporated, in the case of an association with no principal place of business.

3.3 Issuer and TPA Aggregation

Issuers

Within a state and market segment, issuers and their reporting entities must combine the data for all of the plans offered by the same issuer.

If in-network benefits and out-of-network benefits are provided by separate but *affiliated* issuers, data may be reported separately for each type by issuer ***or*** combined and reported by the issuer that provides the in-network coverage.

If two *unaffiliated* issuers provide coverage as part of a package, the issuers must report the data separately. For example, if one issuer provides inpatient coverage and an unaffiliated issuer provides outpatient coverage, the submission for the first issuer should contain only the information about the inpatient coverage and the submission for the other issuer should contain only information about the outpatient coverage.

TPAs and Self-Funded Plans

A TPA reporting on behalf of self-funded plans should, within each state and market segment, combine the data for all of the self-funded plans on whose behalf it is reporting. Self-funded plans are not required to have a TPA report on its behalf. However, we encourage TPAs to submit RxDC reports on behalf of self-funded plans because it will result in fewer submissions and the total amount of data uploaded into HIOS will be much smaller. The combined data is also more useful because a TPA or PBM can determine the Top Drugs based on a larger sample size.

FEHB Carriers

A carrier affiliate or associate such as an issuer, TPA, or other third party such as a vendor or underwriter may be the reporting entity for a FEHB carrier. If a carrier is associated with an issuer, we generally expect that the issuer will report the FEHB line of business in the FEHB market segment of the issuer's submission, rather than the carrier creating a separate submission. Similarly, if a carrier has a contract with a TPA or other third party vendor, we expect the TPA or other third party vendor to report the FEHB line of business data in the FEHB market segment of the TPA's or other third party vendor's submission.

If a carrier chooses to make its own submission, it needs to make sure that the issuer, TPA, or vendor does not report the same data. If a carrier is associated with more than one issuer, TPA, or vendor, the carrier should aggregate data for plans that share the same issuer, TPA, or vendor. If a carrier offers plans that are not associated with an issuer, TPA, or vendor, the carrier should combine the data for those plans.

PBMs

If a PBM is the reporting entity, the rules for aggregating data by issuer and TPA also apply. For example, if a PBM is reporting data for three issuers, the PBM should aggregate the data separately for each issuer. If a PBM is reporting for 10 self-funded plans that have two different TPAs, the PBM should combine the data for the self-funded plans that share each TPA separately.

How do I identify an entity in my submission?
Use the federal Employee Identification Number (EIN) to identify the plan sponsor, issuer, carrier, TPA, or PBM. We cannot rely on the name of the entity as an identifier because different reporting entities might use different spellings.

How do I report data for more than one state, market segment, issuer, or TPA?
Use additional rows in your data files for different states, market segments, and issuers or TPAs. Do not create multiple submissions or upload multiple files of the same type.

3.4 Examples of Aggregated Data Files

Below are examples of aggregated data files.

Example 1: Issuer reports for fully-insured plans

Issuer A reports total spending in California in the individual, small group, and large group markets, and in Washington for the individual and student markets.

EIN	State	Market Segment	Total Spending
EIN for Issuer A	CA	Individual market	$177,141,997
EIN for Issuer A	CA	Small group market	$8,419,411
EIN for Issuer A	CA	Large group market	$23,735,387
EIN for Issuer A	WA	Individual market	$168,409
EIN for Issuer A	WA	Student market	$377,582

Example 2: Issuer reports for multiple issuers in the same holding group

Issuer X, Issuer Y, and Issuer Z are part of the same holding group. Issuer X reports on behalf of itself and also on behalf of Issuer Y and Issuer Z.

EIN	State	Market Segment	Total Spending
EIN for Issuer X	CO	Individual market	$10,437
EIN for Issuer X	CO	Small group market	$333,803,307
EIN for Issuer X	CO	Large group market	$107,047,027
EIN for Issuer X	ID	Large group market	$219,568
EIN for Issuer X	WY	Large group market	$73,114
EIN for Issuer Y	PA	Small group market	$7,234,076
EIN for Issuer Y	PA	Large group market	$231,331,535
EIN for Issuer Y	NY	Small group market	$7,234,076
EIN for Issuer Y	NJ	Small group market	$23,375,484
EIN for Issuer Z	NJ	Small group market	$1,781,722

Example 3: Issuer reports for fully-insured plans, FEHB plans, and self-funded plans

Issuer B (sells insurance and provides administrative services for self-funded plans) reports total spending in Colorado in the individual, small group, and large group markets and for self-funded large employer plans; in Idaho in the individual, small group, and large group markets; and in Wyoming for self-funded large employer plans. Issuer B is also associated with an FEHB carrier and reports for FEHB plans in Colorado.

EIN	State	Market Segment	Total Spending
EIN for Issuer B	CO	Individual market	$58,971,803
EIN for Issuer B	CO	Small group market	$338,403
EIN for Issuer B	CO	FEHB plans	$728,966,601
EIN for Issuer B	CO	SF large employer plans	$219,568
EIN for Issuer B	ID	Individual market	$150,268
EIN for Issuer B	ID	Small group market	$25,441,865
EIN for Issuer B	ID	Large group markets	$1,295,869
EIN for Issuer B	WY	SF large employer plans	$170,953,419

Example 4: TPA reports for self-funded plans

TPA C reports total spending for self-funded small employers and self-funded large employers in multiple states.

EIN	State	Market Segment	Total Spending
EIN for TPA C	KY	SF small employer plans	$162,827,074
EIN for TPA C	KY	SF large employer plans	$404,143,910
EIN for TPA C	LA	SF small employer plans	$370,421
EIN for TPA C	MI	SF small employer plans	$455,249,960
EIN for TPA C	MI	SF large employer plans	$1,077,284,699
EIN for TPA C	MN	SF large employer plans	$2,386,062

Example 5: PBM reports data on behalf of fully-insured plans and self-funded plans

A PBM reports prescription drug rebates for fully-insured plans offered by Issuer D and Issuer E and for self-funded plans administered by TPA F, TPA G, and Issuer D.

EIN	State	Market Segment	Prescription Drug Rebates
EIN for Issuer D	CO	Individual market	$65
EIN for Issuer D	CO	Small group market	$2,278
EIN for Issuer D	CO	Student market	$669,043
EIN for Issuer D's TPA Business	CO	SF small employer plans	$1,372
EIN for Issuer D	WY	Large group market	$456
EIN for Issuer E	PA	Small group market	$45,212
EIN for Issuer E	PA	Large group market	$1,445,822
EIN for TPA F	NY	SF small employer plans	$45,212
EIN for TPA F	NJ	SF small employer plans	$483,284
EIN for TPA G	CT	SF small employer plans	$897,556
EIN for TPA G	CT	SF large employer plans	$296,518

Example 6: Plan sponsor self-reports for fully-insured plans and self-funded plans

An employer with 10,000 employees is headquartered in Nevada and has employees in Nevada, Utah, and Arizona. In each state, employees can choose among several options. Some of the options are fully-insured through Issuer H and some of the plans are self-funded and administered by TPA I. To help facilitate data analysis and identify duplicate submissions, the first column should be the EIN of the issuer or TPA of the plans, rather than the EIN of the plan sponsor. (If a self-funded plan is self-administered and doesn't use a TPA, then you can use the EIN of the plan sponsor.)

EIN	State	Market Segment	Total Spending
EIN for Issuer H	NV	Large group market	$ 9,619,527
EIN for TPA I	NV	SF large employer plans	$34,540,901

4 Premium and Life-Years

Use the definitions in this section to report premium and life-years.

Life-Years

The total number of members covered on a given day of each month of the reference year, divided by 12. For example, for a fictional Plan A:

Month	# of Covered Members
January 1, 2020	882
February 1, 2020	872
March 1, 2020	884
April 1, 2020	921
May 1, 2020	924
June 1, 2020	923
July 1, 2020	925
August 1, 2020	916
September 1, 2020	907
October 1, 2020	906
November 1, 2020	902
December 1, 2020	869
Total Member Months	**10,831**
# of Life-Years (Total member months / 12)	**902.58333333**

Round the number of life-years to the 8th decimal place.

What is a Member?
For the purposes of these instructions, the term member means a person who has health coverage, regardless of whether the coverage is associated with an insurance policy, a group health plan, or an FEHB plan. For example, enrollees, dependents, participants, and beneficiaries are all considered members. Life-years are the average number of members throughout the year.

Earned Premium (fully-insured coverage)

Earned premium means all money paid by a member, policyholder, subscriber, and/or plan sponsor as a condition of the member receiving coverage. Earned premium includes any fees or other contributions associated with the health plan. For FEHB plans, earned premium means the employee and government shares of premium. Report earned premium on a direct basis, without factoring in reinsurance. Include advance payments of the premium tax credit. Do not reduce the amount of earned premium to reflect state or federal MLR rebates.

Premium Equivalents (self-funded coverage)

For self-funded plans and other arrangements that do not rely exclusively or primarily on premiums, report the premium equivalent amounts representing the total cost of providing and maintaining

coverage, including claims costs, administrative costs, Administrative Services Only (ASO) and other TPA fees, and stop-loss premiums.

ASO and Other TPA Fees Paid

Report the ASO and other fees paid to the TPA. This amount should also be included in Premium Equivalents.

Stop Loss Premium Paid

Report the stop loss premium paid to the insurer. This amount should also be included in Premium Equivalents.

Average Monthly Premium

For group plans, report average monthly premium separately according to the amount paid by the employee versus the amount paid by the employer, including for group trust, association, or MEWA plans if employers make premium contributions. Include premium paid on behalf of dependents covered by an employee's plan or coverage.

To calculate average monthly premium, add premium amounts for the reference year, divide by the number of life-years, and then divide by 12.

5 Spending

Report data related specifically to the reference year and paid or received through March 31 of the calendar year immediately following the reference year. For accounting purposes, this is sometimes referred to as "incurred in 12, paid or received in 15."

5.1 Definitions

Total Spending

Report allowed claims with dates of service during the reference year. Allowed claims are the total payments made under the plan or policy to health care providers on behalf of members. Report claims on a direct basis (that is, before reinsurance, unless specifically stated otherwise in these instructions).

Include:

- Payments by the plan, issuer, or carrier
- Cost sharing paid by members
- Claims liability, including claims incurred during the reference year but not paid or not reported as of March 31 of the year following the reference year (such as claims reported but still in the process of adjustment or payment)

Subtract:

- Net payments from any federal or state reinsurance or cost-sharing reduction arrangement or program
- Prescription drug rebates, fees, and other remuneration

Exclude:

- Ineligible claims, such as duplicate claims, recovered claims overpayments, third party liabilities (e.g., coordination of benefits claims), and any other claims that are denied under the policy's or plan's terms
- Payments for services other than medical care (e.g., medical management, quality improvement, and fraud detection and recovery expenses)
- Active life reserves (policy reserves, contract reserves, contingency reserves, or any kind of reserves except traditionally defined reserves for claims incurred but not reported) or change in such reserves
- Charges or payments from the state or federal risk adjustment programs

Total Cost Sharing

Include cost sharing when you report Total Spending, and also as a separate data element.

Include:

Deductibles, coinsurance, and copays, including amounts that may have been paid through a health savings or reimbursement account

Subtract:

- Cost sharing paid by a member's secondary insurance
- Manufacturer cost-sharing assistance (report this in Manufacturer Cost-Sharing Assistance)
- Prescription drug rebates, fees, and other remuneration that are passed to members at the point-of-sale

Exclude:

- Cost sharing reductions the issuer paid on behalf of the member under federal or state cost-sharing reduction programs (include these amounts in total spending but not in total cost sharing)
- Premiums
- Balance billing amounts (report this in Amounts Not Applied to Deductible or Out-of-Pocket Maximum)
- Amounts for items or services not covered by the plan or coverage (report this in Amounts Not Applied to Deductible or Out-of-Pocket Maximum)

Manufacturer Cost-Sharing Assistance

Report manufacturer cost-sharing assistance amounts paid on behalf of members, such as coupons or copay cards, if the cost-sharing assistance reduces spending by the plan, issuer, carrier, or member, to the extent information is available.

Amounts Not Applied to Deductible or Out-of-Pocket Maximum

Report billed amounts that were (1) not applied to a member's deductible or out-of-pocket maximum, (2) not paid by the plan, issuer, or carrier, and (3) not included in Total Spending.

Include:

- Disallowed amounts for non-covered services or for prescription drugs not on a plan or coverage's formulary
- Cost-sharing amounts not applied to the deductible or out-of-pocket maximum. For example, if manufacturer cost-sharing assistance is not counted towards a member's deductible or out-of-

pocket maximum as part of an accumulator adjustment program,[8] you should report those amounts here, as well as in Manufacturer Cost-Sharing Assistance

5.2 Spending Categories

Use the following categories to report spending in the Spending by Category data file. Do not report the same expense in more than one category.

Hospital

Include spending on services provided by hospitals to members and billed by the facility. These include room and board, ancillary charges, services of resident physicians, inpatient pharmacy, hospital-based nursing home and hospice care, and any other services billed by hospitals. Include spending on services provided in psychiatric and substance abuse hospitals. Include spending on facility services for medical, surgical, lab, radiology, therapy, maternity, skilled nursing, and other services that are billed by the facility. Include outpatient care, emergency services, or ambulance services only if billed by the inpatient facility. Include medications dispensed by an institutional pharmacy and administered on-site as part of a medical service. Do not include physician services if the physician independently bills for those services.

Primary Care

Include spending on clinical health care services provided by a primary care provider in a doctor's office or outpatient care center. For the purposes of the RxDC report, a primary care provider is, generally, a physician who (1) has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine and (2) is accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Include spending clinical health care services provided by other clinicians, such as nurse practitioners, clinical nurse specialists, or physician assistants, in a primary care setting. Include spending on obstetrics and gynecology clinical health care services if performed by a primary care provider or clinician.

Include the portion of laboratory and radiology services provided in a primary care setting that are billed independently by the laboratories. Include medications dispensed by an institutional pharmacy and administered on-site as part of a clinical health care service.

Specialty Care

Include spending on clinical health care services provided by specialists in a doctor's office or outpatient care center. Include the portion of laboratory and radiology services associated with specialty care in a doctor's office or outpatient care center that are billed independently by the laboratories. Include services provided in a hospital setting only if the specialist independently bills for those services. Include medications dispensed by an institutional pharmacy and administered on-site as part of a clinical health care service. A specialist is, generally, a provider that focuses on a specific area of medicine or a group of patients to diagnose, manage, prevent, or treat certain types of diseases, symptoms, and conditions. Include spending on clinical health care services by non-physician providers that have training in a specific area of health care. Include clinical health care services provided by chiropractors, podiatrists, optometrists, and physical, occupational, and speech therapists that are not billed as part of hospital services. Do not include dental services or any other amounts reported in another category.

[8] A copay accumulator program, sometimes referred to as accumulator adjustment or maximizer program, is a policy under which the value of manufacturer cost-sharing assistance amounts, such as coupons or copay cards, are not applied to a member's deductible and/or out-of-pocket maximum.

Other Clinical Health Care Services and Equipment

Include spending for all other professional and facility clinical health care services and equipment not reported as hospital, primary care, or specialty care. Include non-hospital based skilled nursing and hospice services. Include spending on ambulance services not billed by a hospital facility. Include spending on home health care, dental and vision services and supplies, durable medical equipment, prosthetic, and orthotics. Do not include spending on wellness services.

Wellness Services

Include expenses for activities primarily designed to implement, promote, and increase health and wellness and not billed as a claim. Examples of wellness services include:

- Wellness assessments
- Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements
- Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition
- Public health education campaigns performed in conjunction with state or local health departments
- Actual rewards, incentives, bonuses, or reductions in cost sharing that are not already reflected in premiums or claims (but not expenses to administer these programs) to the extent permitted by section 2705 of the Public Health Service Act.
- Coaching or education programs and health promotion activities designed to change member behavior (for example, smoking, obesity)

Do not include any service or activity that is not an allowable quality improvement expense for the purposes of calculating the numerator of the federal MLR.

If a wellness expense cannot be tied to a specific plan, issuer, carrier, state, or market segment use a reasonable method to allocate expenses across states and market segments. Describe the method you used in your narrative response form and explain why you believe it is reasonable.

Prescription Drugs

Report spending for prescription drugs covered under the plan or coverage pharmacy benefit. Amounts reported here should not be reported in any other spending category. Spending on prescription drugs should be net of prescription drug rebates, fees, and other remuneration.

Do NOT report spending for drugs covered under non-pharmacy benefit, such as a hospital or medical benefit, in the prescription drug category. Include these amounts in the relevant hospital or medical spending category.

5.3 Example of Data Aggregated by Spending Category

For each EIN, state, and market segment in your data file, use a separate row for each spending category. In the example below, if Issuer J reports individual market data in North Dakota and Wyoming, there would be six rows for each state.

EIN	State	Market Segment	Benefit Category	Total Spending
EIN for Issuer J	ND	Individual market	Hospital	$1,240,100
EIN for Issuer J	ND	Individual market	Primary Care	$459,300
EIN for Issuer J	ND	Individual market	Specialty Care	$873,300

EIN	State	Market Segment	Benefit Category	Total Spending
EIN for Issuer J	ND	Individual market	Other Clinical Health Care Services and Equipment	$428,800
EIN for Issuer J	ND	Individual market	Wellness Services	$3,898
EIN for Issuer J	ND	Individual market	Prescription Drugs	$800,700
EIN for Issuer J	WY	Individual market	Hospital	$311,560
EIN for Issuer J	WY	Individual market	Primary Care	$245,556
EIN for Issuer J	WY	Individual market	Specialty Care	$118,685
EIN for Issuer J	WY	Individual market	Other Clinical Health Care Services and Equipment	$45,019
EIN for Issuer J	WY	Individual market	Wellness Services	$1,642
EIN for Issuer J	WY	Individual market	Prescription Drugs	$225,008

6 Prescription Drug Reporting

6.1 Drug Names

For the purposes of the RxDC report, a prescription drug is defined as a set of National Drug Codes (NDCs) that are grouped together by name and ingredient. This means that drugs are grouped together even if they have different strengths, dosage forms (for example: capsule, tablet, liquid), routes of delivery (ex: oral, injection), labeler names (for example: manufacturer, re-packager, distributer), or package types or sizes. For example, if the same active ingredient can be administered as a tablet or as a liquid, both forms would be considered the same drug for RxDC reporting.

The RxDC drug name is the combination of the ingredient name, the proprietary name, and the proprietary suffix. The names and the suffix are separated from each other using a pipe symbol (" | "), with a space on both sides of the pipe symbol. If a drug has two or more active ingredients, the RxDC drug name generally includes all of the active ingredients. However, the ingredient names are not separated from each other by a pipe symbol.

The table below shows three NDC codes for APRISO, which is a proprietary version of the drug mesalamine. The NDCs are considered the same drug for RxDC reporting even though they have different labeler names and package descriptions.

NDC	Strength	Dosage Form	Route	Labeler Name	Package Description	RxDC Drug Name
65649-103-01	375 mg/1	CAPSULE, EXTENDED RELEASE	ORAL	Salix Pharmaceuticals, Inc.	1 BOTTLE in 1 CARTON (65649-103-01) > 4 CAPSULE, EXTENDED RELEASE in 1 BOTTLE	Mesalamine | APRISO
65649-103-02	375 mg/1	CAPSULE, EXTENDED RELEASE	ORAL	Salix Pharmaceuticals, Inc.	1 BOTTLE in 1 CARTON (65649-103-02) > 120 CAPSULE, EXTENDED RELEASE in 1 BOTTLE	Mesalamine | APRISO
43353-884-79	375 mg/1	CAPSULE, EXTENDED RELEASE	ORAL	Aphena Pharma Solutions - Tennessee, LLC	2160 CAPSULE, EXTENDED RELEASE in 1 BOTTLE (43353-884-79)	Mesalamine | APRISO

If a drug has more than one proprietary name, the proprietary versions are grouped separately from each other. For example, in the table below, mesalamine has 10 proprietary versions and one non-proprietary version. Each row is a unique prescription drug for RxDC reporting purposes.

Ingredient	Proprietary Name	Proprietary Name Suffix	Number of Associated NDCs	RxDC Drug Name
Mesalamine	n/a		51	Mesalamine
Mesalamine	APRISO		3	Mesalamine | APRISO
Mesalamine	Asacol HD		1	Mesalamine | Asacol HD
Mesalamine	Canasa		3	Mesalamine | Canasa
Mesalamine	Delzicol		2	Mesalamine | Delzicol
Mesalamine	Lialda		4	Mesalamine | Lialda
Mesalamine	Pentasa		2	Mesalamine | Pentasa
Mesalamine	Rowasa		2	Mesalamine | Rowasa
Mesalamine	sfRowasa	Sulfite-Free Formulation	2	Mesalamine | sfRowasa | Sulfite-Free Formulation
Mesalamine	ZALDYON		4	Mesalamine | ZALDYON

CMS will provide a crosswalk or instructions to map each NDC to the relevant RxDC prescription drug name. You must use the crosswalk or instructions provided by CMS and may not use a different system for classifying drugs. If the CMS crosswalk is missing an NDC for a prescription drug that was dispensed during the reference year, you should map the NDC to the relevant RxDC drug name using the naming method described here. Provide the NDC and RxDC drug name in the narrative response.

6.2 Therapeutic Classes

A therapeutic class is a group of drugs that have a similar mechanism of action or treat the same types of conditions. For example, mesalamine might be grouped with other drugs that reduce inflammation in the lining of the intestine to form a therapeutic class called Inflammatory Bowel Disease Agents | Aminosalicylates.

RxDC Drug Name	Number of Associated NDCs	RxDC Therapeutic Class
BALSALAZIDE DISODIUM	10	Inflammatory Bowel Disease Agents | Aminosalicylates
BALSALAZIDE DISODIUM | COLAZAL	1	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE	51	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | APRISO	3	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | ASACOL HD	1	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | CANASA	3	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | DELZICOL	2	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | LIALDA	4	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | PENTASA	2	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | ROWASA	2	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | SFROWASA | SULFITE FREE FORMULATION	2	Inflammatory Bowel Disease Agents | Aminosalicylates
MESALAMINE | ZALDYON	4	Inflammatory Bowel Disease Agents | Aminosalicylates

RxDC Drug Name	Number of Associated NDCs	RxDC Therapeutic Class
SULFASALAZINE	39	Inflammatory Bowel Disease Agents | Aminosalicylates
SULFASALAZINE | AZULFIDINE	4	Inflammatory Bowel Disease Agents | Aminosalicylates
SULFASALAZINE | AZULFIDINE | EN TABS	4	Inflammatory Bowel Disease Agents | Aminosalicylates

Generally, NDCs that are grouped together with the same RxDC drug name will also be grouped together in the same RxDC therapeutic class. However, there can be exceptions to that rule. CMS will provide a crosswalk or instructions to map each NDC to a therapeutic class for RxDC reporting purposes. You must use the crosswalk or instructions provided by CMS and may not use a different system to assign a therapeutic class.. If the CMS crosswalk is missing an NDC for a drug that was prescribed during the reference year, you should map the NDC to the RxDC therapeutic class that you believe is most relevant. Provide the NDC and the RxDC therapeutic class in the narrative response.

Where can I download the CMS Drug and Therapeutic Class Crosswalk File?
CMS intends to post the crosswalk file within the RxDC module in HIOS. If there is a delay in posting the crosswalk file, CMS will provide instructions on how you should create your own crosswalk.

6.3 Rx Utilization

Use the following definitions to report prescription drug utilization.

Number of Paid Claims

The number of claims paid for prescriptions filled during the reference year.

Number of Members with a Paid Claim

The number of members with at least one paid claim for a prescription filled during the reference year.

Total Dosage Units

The total number dosage units dispensed during the reference year. Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

6.4 Rx Spending

Use the definitions in Section above for Total Spending, Total Cost Sharing, and Manufacturer cost-sharing assistance. Total spending and total cost sharing are net of prescription drug rebates, fees, and other remuneration.

6.5 Rx Totals Table

The Rx Totals table includes columns for bona fide service fees and PBM spread amounts, which are not in any other tables. It is also the only table where you report information for drugs covered under a non-pharmacy benefit. Use the definitions below when populating the Rx Totals table.

Drugs Covered Under a Non-Pharmacy Benefit

In the Rx Totals table, report spending for drugs covered under a non-pharmacy benefit, such as a medical or hospital benefit. Sometimes the cost of prescription drugs covered by a non-pharmacy benefit is not readily available, such as when it is part of some bundled payment arrangements or other alternative payment arrangements. You must make a good faith effort to obtain the information on these costs to the best of your ability. If you are nonetheless unable to identify these amounts, estimate the portion of spending attributable to prescription drugs included in the bundle or other alternative payment arrangement. If you use an estimate, explain the circumstances and describe the method used in the narrative response.

Bona Fide Service Fees

Bona fide service fees are fees that a manufacturer pays to a PBM that:

- Represent fair market value for a bona fide, itemized service performed on behalf of the manufacturer. These are services that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and
- Are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

PBM Spread Amounts

The PBM spread is the difference between the amount the plan, issuer, or carrier paid to the PBM and the amount the PBM paid to manufacturers, wholesalers, pharmacies, or other vendors. For example, if plans paid $250 to the PBM, and the PBM paid $200 to manufacturers, wholesalers, pharmacies, or other vendors, the PBM spread amount would be $50.

Include:

- amounts for all drugs furnished through the PBM.
- amounts paid to retail, mail-order, and other pharmacies.

If a plan, issuer, or carrier uses pass-through pricing to pay PBMs, use zero for the PBM spread amount. If a plan, issuer, or carrier uses lock-in pricing to pay PBMs, report the difference between the lock-in price and the price ultimately received by the pharmacy.

6.6 Top Drug Lists

Exclude drugs covered under a non-pharmacy benefit when you create the four RxDC top drug tables. If there are ties when you rank the top drugs, use the number of members with a paid claim as the tie breaker. If there is still a tie, choose one of the other utilization or spending measures to break the tie.

Top 50 Most Frequently Dispensed Brand Name Drugs

Use the following steps to create the Top 50 Most Frequent Brand Name Drugs table.

1. For each RxDC brand name drug, calculate the total number of paid claims in a state and market by adding the number of paid claims for every NDC associated with the RxDC brand drug name.
    - Only count paid claims for prescriptions filled during the reference year
    - If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market for the issuer or TPA.
    - CMS will indicate which drugs are considered brand name drugs in the CMS Drug and Therapeutic Class Crosswalk File, or provide instructions for you to determine which drugs are considered brand name drugs.

2. Rank the drugs in each state and market segment according to number of paid claims. Using this ranking, identify the 50 brand name drugs with the highest number of paid claims.
3. Create a table with the top 50 drugs and include a row for every state, market segment, and EIN of the issuer or TPA.[9]
    - This means that there will be 50 rows for every state, market segment, and EIN combination.
4. For each row, report the number of paid claims and the other utilization and spending variables in the file layouts.

Top 50 Most Costly Drugs

Use the following steps to create the Top 50 Most Costly Drugs table.

1. For each RxDC drug, calculate total spending, net of prescription drug rebates, fees, and other remuneration, in the state and market segment by summing total spending for every NDC associated with the RxDC drug name.
    - Use the definition of Total Spending in Section 5.1 above.
    - If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market for the issuer or TPA.
2. Rank the drugs in the state and market segment according to total spending and identify the 50 drugs with the greatest total spending.
3. Create a table with the top 50 drugs and include a row for every state, market segment, and EIN of the issuer or TPA.
    - This means that there will be 50 rows for every state, market segment, and EIN combination.
4. For each row, report total spending and the other utilization and spending variables in the file layouts.

Top 50 Drugs with the Greatest Increase in Spending

Use the following steps to create the Top 50 Drugs with the Greatest Increase in Spending table. Exclude prescription drugs if they were not approved for marketing, or issued an Emergency Use Authorization (EUA), by the Food and Drug Administration for the entire reference year *and* for the entire calendar year immediately preceding the reference year.

1. For each RxDC drug, calculate total spending, net of prescription drug rebates, fees, and other price concessions, in the state and market segment by summing total spending <u>for the reference year</u> for the NDCs associated with the RxDC drug name.
    - Use the definition of Total Spending in Section 5.1 above.
    - Only include NDCs if they were approved for marketing or issued an EUA for all of the reference year and for all of the year prior to the reference year.
    - If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market for the issuer or TPA.
2. For each RxDC drug, calculate total spending, net of prescription drug rebates, fees, and other price concessions, in the state and market segment <u>for the year prior to the reference year</u> by summing total spending for the NDCs associated with the RxDC drug name.
    - Use the definition of Total Spending in Section 5.1 above.

[9] When we say the "EIN of the issuer or TPA", this is a shorthand way of referring to the EIN of the relevant issuer, TPA, carrier, or plan according to the Aggregation section above. Similarly, "market" or "market segment" in this section 6.5 also refers to FEHB line of business as appropriate.

- Only include NDCs if they were approved for marketing or issued an EUA for all of the reference year and for all of the year prior to the reference year.
- If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market for the issuer or TPA.

3. For each RxDC drug, calculate the increase in total spending by subtracting total spending in the state and market segment for the year prior to the reference year (the amount from Step 2) from total spending in the state and market segment for the reference year (the amount from Step 1).
    - If spending on a drug increased from one year to the next, the difference will be a positive number. If spending on a drug decreased from one year to the next, the difference will be a negative number.
4. Rank the drugs in each state and market segment according to the increase in total spending (the amount from Step 3). Identify the 50 drugs with the greatest increase in total spending.
    - Use the dollar amount increase, not the percent increase.
5. Create a table with the top 50 drugs and include a row for every state, market segment, and EIN of the issuer or TPA.
    - This means that there will be 50 rows for every state, market segment, and EIN combination.
6. For each row, report total spending in the reference year, total spending in the year prior to the reference year, the increase in total spending, and the other utilization and spending variables in the file layouts.

Top 25 Drugs with the Greatest Amount of Rebates

Use the following steps to create the Top 25 by Rx Rebates table.

1. For each RxDC drug, calculate total rebates, fees, and other remuneration in the state and market segment by summing total rebates, fees, and other remuneration for every NDC associated with the RxDC drug name.
    - Use the definition of Total Rebates, Fees, and Other Remuneration in Section below.
    - If Rx rebates, fees, and other remuneration cannot be measured at the NDC level, use a reasonable method to allocate rebates, fees, and other remuneration to the NDC level. See Section below for more information about allocation methods.
2. Rank the drugs in the state and market segment according to total rebates, fees, and other remuneration and identify the 25 drugs with the greatest amount.
3. Create a table with the top 25 drugs and include a row for every state, market segment, and EIN of the issuer or TPA.
    - This means that there will be 25 rows for every state, market segment, and EIN combination.
4. For each row, report prescription drug rebates, fees, and other remuneration, as well as the utilization, spending, and other associated Rx rebate variables in the file layouts.

7 Prescription Drug Rebates, Fees, and Other Remuneration

7.1 Definitions

Pharmacy benefit manager

Pharmacy benefit manager (PBM) generally means an entity that, either directly or through an intermediary, acts as a price negotiator, manages the prescription drug benefits, or provides other

pharmacy benefit management services to the plan, issuer, or carrier. Pharmacy benefit management services include processing and paying of prescription drug claims, performing drug utilization review, processing prior authorization requests, adjudicating appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, designing formularies, and controlling the cost of covered prescription drugs.

Rebates retained by PBMs

- Include manufacturer rebates received by PBMs and not passed through to any member or entity
- Include amounts received directly from a manufacturer or indirectly from a pharmacy, wholesaler, or other entity Include rebate amounts that are expected but have not yet been received if the PBM will retain the expected amounts

Rebates retained by plans/issuers/carriers

- Include manufacturer rebates received by plans, issuers, or carriers and not passed through to any member or entity
- Include amounts received directly from a manufacturer or indirectly from a PBM, pharmacy, wholesaler, or other entity
- Include rebate amounts that are expected but have not yet been received if the plan, issuer, or carrier will retain the expected amounts
- Include rebate guarantee amounts. A rebate guarantee amount is a payment received from a PBM to account for the difference between the rebate amount guaranteed by a PBM, as likely delineated in the contract between the two parties, and the actual rebate amount received from a drug manufacturer

Rebates passed to members at POS

- Include manufacturer rebates passed through (rather than retained by PBMs or plans/issuers/carriers) to members at the point of sale (POS)
- Exclude manufacturer cost-sharing assistance

Net transfer of other remuneration from manufacturers to plans/issuers/carriers/PBMs

Report *net* amounts. For example, if transfers from manufacturer to a PBM exceed transfers from the PBM to manufacturer, report a positive number. If transfers from a PBM to the manufacturer exceed transfers from the manufacturer to the PBM, report a negative number.

- Include price concessions, fees, and other remuneration provided to a plan, issuer, carrier, or PBM, directly or indirectly. For example, include the following amounts:
    - Bona fide service fees
    - Discounts
    - Chargebacks
    - Cash discounts
    - Free goods contingent on a purchase agreement
    - Up-front payments
    - Coupons
    - Goods in kind
    - Free or reduced-price services
    - Grants
    - Other price concessions or similar benefits
- Include fees and other remuneration that are expected but not yet transferred

- Exclude any remuneration, coupons, or price concessions for which the full value is passed on to the member

Net transfer of other remuneration from pharmacies to issuers/plans/carriers/PBMs

Report the amounts described above (in the data element for the net transfer of other remuneration from manufacturers to issuers, plans, carriers, and PBMs) except that the amount reported here should be the net transfer from pharmacies, wholesalers, and other entities, rather than from manufacturers.

Report *net* amounts. For example, if transfers from pharmacies to a PBM exceed transfers from the PBM to pharmacies, report a positive number; if transfers from a PBM to pharmacies exceed transfers from pharmacies to the PBM, report a negative number.

Total rebates, fees, and other remuneration

Sum of the previous five data elements.

Restated prior year rebates, fees, and other remuneration

Restate total rebates and other remuneration from the prior reference year as of 3/31 of the calendar year following the current reference year (that is, incurred in 12 months, paid or received in 27 months). So, for example, in the 2021 RxDC report, there would be one column for total rebates for 2021 (as of 3/31/2022) and another column for restated rebates for 2020 (restated as of 3/31/2022). This field is required starting with the RxDC report for the 2021 reference year.

7.2 Allocation Methods

Use a reasonable method to allocate rebates, fees, and other remuneration if they cannot be tied to a specific prescription drug for a specific EIN, state, and market segment.

Here are examples of reasonable and unreasonable methods to allocate prescription drug rebates.

Method	Description	Reasonable?	Explanation
Based on dosage units	Allocate rebates received for multiple drugs based on total dosage units for each drug as a percent of total drug spending for all the prescription drugs for which the rebate was received.	Yes	Appropriately accounts for differences in a specific drug’s utilization across plans and issuers.
Based on total drug spending	Allocate rebates received for multiple drugs based on total drug spending for each drug as a percent of total drug spending for all the prescription drugs for which the rebate was received.	Yes	Approximates differences in utilization and spending on rebate eligible drugs.
Based on billed rebate amounts	Rebates received for a specific drug are allocated to a plan, issuer, or carrier and 11-digit NDC based on the rebate amounts billed to the pharmaceutical manufacturer for the specific plan, issuer, or carrier and drug as a percent of the total rebate amount billed to the pharmaceutical manufacturer for all of the PBM’s plans or issuers.	Yes	Appropriately accounts for differences in a specific drug’s utilization across plans or issuers.
Based on plan’s brand	Rebate amounts received for multiple drugs are allocated to a plan, issuer, or	Yes, but only if the PBM	Accounts for differences in

Method	Description	Reasonable?	Explanation
drug spending	carrier based on the total drug spend for drugs under the plan, issuer, or carrier as a percent of the total drug spend for brand drugs under all of the PBM's plans or issuers, and further to a prescription drug based on the NDC-specific total drug spend under the plan, issuer, or carrier as a percent of the total drug spend for brand drugs under the plan, issuer, or carrier.	receives rebates only for brand drugs.	utilization and spending on rebate-eligible drugs across plans or issuers.
Based on enrollment	Rebates received for multiple drugs are allocated to a plan, issuer, or carrier for prescription drug based on the number of members enrolled in the plan, issuer, or carrier as a percent of the total number of members enrolled in all of the PBM's plans, issuers or carriers.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across plans or issuers.
Based on the number of paid claims	Rebates received for multiple drugs are allocated to a plan, issuer, or carrier for prescription drugs based on the number of claims under the plan, issuer, or carrier as a percent of the total number of claims received under all of the PBM's plans, issuers or carriers. Thus, allocation is based on the total number of claims for all of the drugs rather than the number of claims received for each drug.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across plans or issuers.

Describe the method you used in the narrative response. If you used an allocation method other than one of the methods described as reasonable in the table above, Include enough detail for CMS to evaluate whether the method is reasonable.

Also describe the methods you used to allocate fees or other remuneration in the narrative response. Some allocation methods, such as allocation based on the number of paid claims, are considered unreasonable for allocating rebates but might, based on the support that you provide in the narrative response, be considered reasonable for allocating fees.

8 Narrative Response

Address the following topics in your narrative response. Save your narrative as a Word document or pdf before uploading it into HIOS.

Employer size for self-funded plans

Did you use actual counts or estimates to determine the size of the employer for self-funded plans? Describe your estimation method if you used estimates.

Wellness services

Describe the wellness services related to expenses reported in the Wellness Service spending category. Describe allocation methods, if applicable.

Drugs missing from the CMS crosswalk

If the CMS crosswalk is missing an NDC for a drug that was prescribed during the reference year and covered under the pharmacy benefit, provide the RxDC drug name and therapeutic class that you used.

Drugs covered under hospital or medical benefits

Describe the methods you used to measure spending on drugs covered under the hospital or medical benefits. Describe allocation methods, if applicable.

Prescription drug rebate descriptions

Describe the types of rebates, fees, and other remuneration that you included or excluded in the Rx Totals, Rx Rebates by Therapeutic Class, and Rx Rebates for the Top 25 Drugs . Explain any negative values for rebates, fees, or other remuneration.

Allocation methods for prescription drug rebates

Describe the methods you used to allocate prescription drug rebates, fees, and other remuneration. If you used an allocation method other than one of the methods described as reasonable in the table above, your description must include enough detail for CMS to evaluate whether the method is reasonable.

Impact of prescription drug rebates

Describe the impact of rebates, fees, and other remuneration on premium and out-of-pocket costs in your narrative response. Provide as much detail as possible. Describe how and why the impact may vary based on the market segment or for particular types of plans, such as high deductible health plans. Describe the impact of prescription drug rebates on the tier assignment of prescription drugs in the formulary, or the removal of generic equivalents from a formulary. If possible, provide a quantitative estimate of the impact.

Appendix A: File Layouts for the RxDC Report

To complete a RxDC data submission, a reporting entity needs to upload the plan list and data files described below. Multiple entities may upload files on behalf of a plan, issuer, or carrier. The files need to meet the requirements outlined in this document, regardless of who uploads the files.

Important Notes:

- **The files you upload must be in comma-separated values (csv) format.**
- **Do not use commas in your data before saving it as a csv file.**
  For example, enter "My Company Inc", not "My Company, Inc".
- **The order of the columns in your file must exactly match the order of the columns in the file layouts below.**

P1: Individual and Student Market Plan List

Column Name	Field Type	Instructions
HIOS Plan Name	String	Do not use commas.
HIOS Plan ID	String	14-digit HIOS Plan ID. Do not use dashes. Ex: 12345NY1234567.
Plan Beginning Date	Date	MM/DD/YYYY Usually this is January 1 of the reference year. If the plan year isn't the same as the calendar year, report the beginning and end dates of the plan year that ends during the reference year.
Plan End Date	Date	MM/DD/YYYY Usually this is December 31 of the reference year. If the plan year isn't the same as the calendar year, report the beginning and end dates of the plan year that ends during the reference year.
Market Segment	String	Valid Values: Individual market Student market
Members as of 12/31	Integer	The number of enrollees on the last day of the reference year.
PBM Name	String	If there is more than one value, separate them with a semicolon.
PBM EIN	String	9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.

P2: Group Health Plan List

Column Name	Field Type	Instructions
Group Health Plan Name	String	Do not use commas. Do not include FEHB plans.
Group Health Plan Number	String	Enter a unique plan identification number. You can use the identification number in your own database or any other numbering sequence as long as there is a unique plan ID number for every plan.
HIOS Plan ID	String	If applicable, enter the 14-digit HIOS Plan ID(s). Do not use dashes. Ex: 12345NY1234567. If there is more than one value, separate them with a semicolon.

Column Name	Field Type	Instructions
Form 5500 Plan Number	String	If applicable, enter the 3-digit plan number reported on the IRS Form 5500 filed with the Department of Labor. If there is more than one value, separate them with a semicolon.
States in which the plan offered	String	Enter the state(s) in which the plan or coverage is offered using 2-character state postal code.[10] If there is more than one state, separate them with a semicolon. For example: AL; AK; MA. If a plan is offered in every state and in DC, enter "National". If a plan is offered nationally and also in the territories, enter "National" as well as the 2-character postal code for the territories, separated by a semicolon. For example: National; PR; GU.
Market Segment	String	<u>Valid Values</u>: Small group market Large group market SF small employer plans SF large employer plans
Plan Beginning Date	Date	MM/DD/YYYY Usually this is January 1 of the reference year. If the plan year isn't the same as the calendar year, report the beginning and end dates of the plan year that ends during the reference year.
Plan End Date	Date	MM/DD/YYYY Usually this is December 31 of the reference year. If the plan year isn't the same as the calendar year, report the beginning and end dates of the plan year that ends during the reference year.
Members as of 12/31	Integer	The number of members with coverage, including dependents, on the last day of the reference year.
Plan Sponsor Name	String	Enter the plan sponsor or client name. If there is more than one value, separate them with a semicolon.
Plan Sponsor EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.
Issuer Name	String	If there is more than one value, separate them with a semicolon.
Issuer EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. Ex: 001234567. If there is more than one value, separate them with a semicolon.
TPA Name	String	If there is more than one value, separate them with a semicolon.
TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.

[10] In these instructions, the term "State" includes the District of Columbia and the U.S. territories. For Federal Employee Health Benefit (FEHB) plans, you must report data for the territories. For other plans, reporting on territories is optional.

Column Name	Field Type	Instructions
PBM Name	String	If there is more than one value, separate them with a semicolon.
PBM EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.

P3: FEHB Plan List

Column Name	Field Type	Instructions
FEHB Plan Name	String	Do not use commas.
FEHB Contract Number	String	Enter the FEHB Contract ID
FEHB Plan Code	String	Enter the two-digit FEHB plan code as it appears in the FEHB plan brochure. Separate each two-digit plan code with a semicolon.
States in which the plan is offered	String	Enter the states and territories in which the plan is offered using the 2-character postal code. If there is more than one state or territory, separate them with a semicolon. For example: AL; AK; MA. If a plan is offered in every state and in DC, enter "National". If a plan is offered nationally and also in the territories, enter "National" as well as the 2-character postal code for the territories, separated by a semicolon. For example: National; PR; GU
Plan Beginning Date	Date	MM/DD/YYYY Usually this January 1. If the plan year isn't the same as the calendar year, report the beginning and end dates of the plan year than ends during the reference year.
Plan End Date	Date	MM/DD/YYYY Usually this is December 31. If the plan year isn't the same as the calendar year, report the beginning and end dates of the plan year than ends during the reference year.
Members as of 12/31	Integer	The number of FEHB covered individuals, including dependents, on the last day of the reference year.
FEHB Carrier Name	String	Do not use commas.
FEHB Carrier EIN	String	9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567.
Affiliate Name	String	(If different from the FEHB carrier.) Do not use commas. If there is more than one value, separate them with a semicolon.
Affiliate EIN	String	(If different from the FEHB carrier.) Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. Ex: 001234567. If there is more than one value, separate them with a semicolon.
TPA or other Third Party Name	String	(If different from the FEHB carrier.) Enter the Do not use commas. If there is more than one value, separate them with a semicolon.

Column Name	Field Type	Instructions
TPA or other Third Party EIN	String	(If different from the FEHB carrier.) Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. Ex: 001234567. If there is more than one value, separate them with a semicolon.
PBM Name	String	(If different from the FEHB carrier.) Enter the Do not use commas. If there is more than one value, separate them with a semicolon.
PBM EIN	String	(If different from the FEHB carrier.) Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.

D1: Premium and Life Years

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do not enter more than one value.**
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more than one value.**
State	String	Enter the 2-character state or territory postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	Valid Values: Individual market Student market Small group market Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Average Monthly Premium Paid by Employees	Numeric	
Average Monthly Premium Paid by Employers	Numeric	
Life Years	Numeric	
Earned Premium	Numeric	For fully-insured plans.
Premium Equivalents	Numeric	For self-funded plans.
ASO/TPA Fees Paid (included in the Premium Equivalents field)	Numeric	For self-funded plans.
Stop Loss Premium Paid (included in the Premium Equivalents field)	Numeric	For self-funded plans.

D2: Spending by Category

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do not enter more than one value.**
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more than one value.**
State	String	Enter the 2-character state postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	<u>Valid Values</u>: Individual market Student market Small group market Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Spending Category	String	<u>Valid Values</u>: Hospital Primary Care Specialty Care Other Clinical Health Care Services and Equipment Wellness Services Prescription Drugs **Do not enter more than one value.**
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum	Numeric	

D3: Top 50 Most Frequent Brand Drugs

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do not enter more than one value.**
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more than one value.**
State	String	Enter the 2-character state postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	<u>Valid Values</u>: Individual market Student market Small group market

Column Name	Field Type	Instructions
		Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Drug Name	String	Enter the drug name from the CMS crosswalk file. **Do not enter more than one value.**
Drug Code	String	Enter the drug code from the CMS crosswalk file. Do not use NDC. **Do not enter more than one value.**
Frequency Rank	Integer	Valid Values: 1-50. **Do not enter more than one value.**
Number of Paid Claims	Integer	
Number of Members with a Paid Claim	Integer	
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	

D4: Top 50 Most Costly Drugs

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do not enter more than one value.**
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more than one value.**
State	String	Enter the 2-character state postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	Valid Values: Individual market Student market Small group market Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Drug Name	String	Enter the drug name from the CMS crosswalk file. **Do not enter more than one value.**
Drug Code	String	Enter the drug code from the CMS crosswalk file. Do not use NDC. **Do not enter more than one value.**
Cost Rank	Integer	Valid Values: 1-50. **Do not enter more than one value.**
Number of Paid Claims	Integer	
Number of Members with a Paid Claim	Integer	
Number of Dosage	Numeric	

Units		
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	

D5: Top 50 Drugs by Spending Increase

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do not enter more than one value.**
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more than one value.**
State	String	Enter the 2-character state postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	Valid Values: Individual market Student market Small group market Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Drug Name	String	Enter the drug name from the CMS crosswalk file. **Do not enter more than one value.**
Drug Code	String	Enter the drug code from the CMS crosswalk file. Do not use NDC. **Do not enter more than one value.**
Spending Increase Rank	Integer	Valid Values: 1-50. **Do not enter more than one value.**
Number of Paid Claims	Integer	
Number of Members with a Paid Claim	Integer	
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	
Prior Year Number of Paid Claims	Integer	
Prior Year Number of Members with a Paid Claim	Integer	
Prior Year Number of Dosage Units	Numeric	
Prior Year Total Spending	Numeric	
Prior Year Total Cost Sharing	Numeric	
Prior Year Manufacturer	Numeric	

Column Name	Field Type	Instructions
Cost-Sharing Assistance		
Dollar Increase in Total Spending	Numeric	

D6: Rx Totals

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do not enter more than one value.**
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more than one value.**
State	String	Enter the 2-character state postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	Valid Values: Individual market Student market Small group market Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Total Rx Spending under Pharmacy Benefit	Numeric	
Total Rx Spending under Non-Pharmacy Benefits	Numeric	
Bona Fide Service Fees	Numeric	
PBM Spread Amounts	Numeric	
Total Rebates/Fees/Other Remuneration	Numeric	
Restated Prior Year Rebates/Fees/Other Remuneration	Numeric	

D7: Rx Rebates by Therapeutic Class

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do not enter more than one value.**
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more**

Column Name	Field Type	Instructions
		than one value.
State	String	Enter the 2-character state postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	Valid Values: Individual market Student market Small group market Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Therapeutic Class Name	String	Enter the therapeutic class name from the CMS crosswalk file. **Do not enter more than one value.**
Therapeutic Class Code	String	Enter the therapeutic class code from the CMS crosswalk file. **Do not enter more than one value.**
Number of Paid Claims	Integer	
Number of Members with a Paid Claim	Integer	
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	
Rebates Retained by PBM	Numeric	
Rebates Retained by Plan/Issuer/Carrier	Numeric	
Rebates Passed to Member at POS	Numeric	
Net Transfer of Fees and Other Remuneration from Manufacturer to Plan/Issuer/Carrier	Numeric	
Net Transfer of Fees and Other Remuneration from Pharmacy to Plan/Issuer/Carrier	Numeric	
Total Rebates/Fees/Other Remuneration	Numeric	
Restated Prior Year Rebates/Fees/Other Remuneration	Numeric	

D8: Rx Rebates for the Top 25 Drugs

Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not use commas. **Do**

Column Name	Field Type	Instructions
		not enter more than one value.
Issuer or TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN has fewer than 9 digits. Do not use dashes. Ex: 001234567. **Do not enter more than one value.**
State	String	2-character state postal code. Ex: NY. **Do not enter more than one value.**
Market Segment	String	Valid Values: Individual market Student market Small group market Large group market SF small employer plans SF large employer plans FEHB plans **Do not enter more than one value.**
Drug Name	String	Enter the drug name from CMS crosswalk file. **Do not enter more than one value.**
Drug Code	String	Enter the drug code from the CMS crosswalk. Do not use NDC. Do not enter more than one value.
Rebate Rank	Integer	Valid Values: 1-25. **Do not enter more than one value.**
Number of Paid Claims	Integer	
Number of Members with a Paid Claim	Integer	
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	
Rebates Retained by PBM	Numeric	
Rebates Retained by Plan/Issuer/Carrier	Numeric	
Rebates Passed to Member at POS	Numeric	
Net Transfer of Fees and Other Remuneration from Manufacturer to Plan/Issuer/Carrier	Numeric	
Net Transfer of Fees/Other Remuneration from Pharmacy to Plan/Issuer/Carrier	Numeric	
Total Rebates/Fees/Other Remuneration	Numeric	
Restated Prior Year Rebates/Fees/Other Remuneration	Numeric	